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Chapter 59: Colorectal Cancer

INTRODUCTION

- *Colorectal cancer* (CRC) is a malignant neoplasm involving the colon, rectum, and anal canal.

PREVENTION AND SCREENING

- *Primary prevention* strategies aim to prevent CRC in an at-risk population. Aspirin and nonaspirin nonsteroidal anti-inflammatory drugs are chemopreventative agents, with use limited to patients with Lynch syndrome or familial adenomatous polyposis.
- *Secondary prevention* approaches are undertaken to prevent malignancy in a population that has already manifested an initial disease process. Consider aspirin 325 mg daily in survivors of CRC.
- In recognition of the increasing incidence of CRC in adults younger than 50 years, national organizations recommend initiating CRC screening at age 45 for individuals at average risk for CRC.

CLINICAL MANIFESTATIONS

- Signs and symptoms of CRC can be extremely varied and nonspecific. Early-stage CRC is often asymptomatic and detected by screening procedures.
- Blood in the stool is the most common sign; however, any change in bowel habits, abdominal discomfort, or abdominal distention may be a warning symptom. Less common signs and symptoms include nausea, vomiting, and, if anemia is severe, fatigue.
- Twenty percent of patients present with metastatic disease most commonly in the liver, lungs, and bones.

DIAGNOSIS

- Workup includes physical examination, personal and family history, evaluation of the entire large bowel by colonoscopy, baseline laboratory tests, radiographic imaging studies, and serum carcinoembryonic antigen (CEA). Serum CEA is a marker for monitoring CRC response to treatment, but it is too insensitive and nonspecific to be used as a screening test for early-stage CRC.
- Determine CRC stage to predict prognosis and develop treatment options. Stage is based on size of the primary tumor ($T_{1–4}$), presence and extent of lymph node involvement ($N_{0–2}$), and presence or absence of distant metastases (M).
  - ✓ Stage I disease involves tumor invasion of the submucosa (T_1) or muscularis propria (T_2) and negative lymph nodes.
  - ✓ Stage II disease involves tumor invasion through the muscularis propria into pericolorectal tissues (T_3), or penetration to the surface of the visceral peritoneum (T_{4a}), or directly invades or is adherent to other organs or structures (T_{4b}), and negative lymph nodes.
  - ✓ Stage III disease includes $T_{1–4}$ and positive regional lymph nodes.
  - ✓ Stage IV disease includes any T, any N, and distant metastasis.

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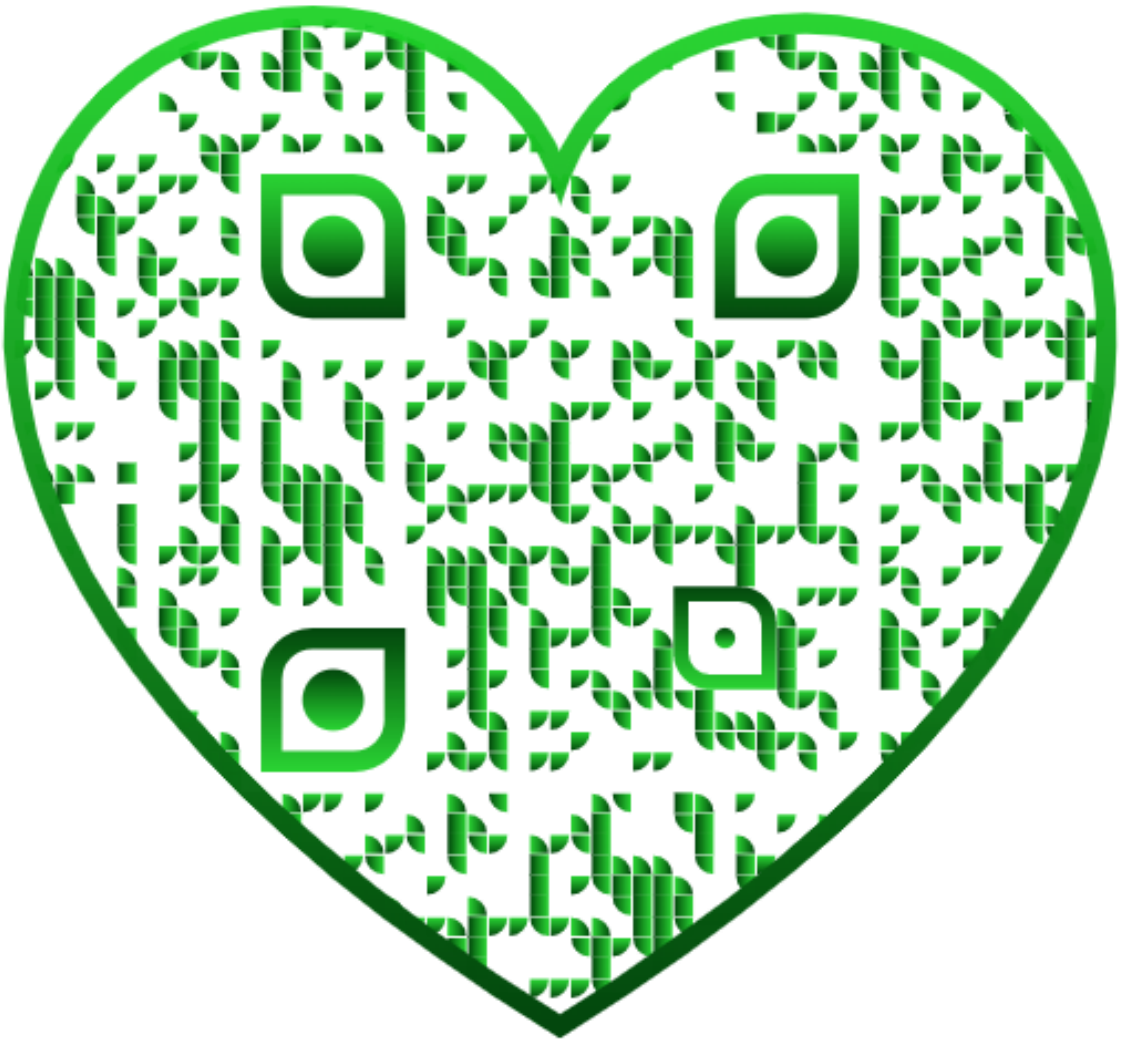

PROGNOSIS

- Stage at diagnosis is the most important independent prognostic factor for survival and disease recurrence. Five-year relative survival is approximately 90% for those with localized tumor as compared with about 16% for those with metastatic disease at diagnosis.
- Poor prognostic clinical factors at diagnosis include bowel obstruction or perforation, high preoperative CEA level, distant metastases, and location of the primary tumor in the rectum or rectosigmoid area.
- Molecular markers, particularly microsatellite instability (MSI), 18q/*DCC* mutation or LOH, *BRAF V600E* mutation, and *RAS* mutations are also associated with CRC prognosis, although the pathologic stage of disease remains the primary prognostic assessment.

TREATMENT

- Goals of Treatment: The goals include cure for stages I, II, and III; the intent is to eradicate micrometastatic disease after surgical resection. Most stage IV disease is incurable; palliative treatment is given to reduce symptoms, avoid disease-related complications, and prolong survival. Twenty to 30% of patients with metastatic disease may be cured if their metastases are resectable.
- Treatment modalities are surgery, radiation therapy (RT), chemotherapy, and biomodulators.

OPERABLE DISEASE

SURGERY

- Complete surgical resection of the primary tumor with regional lymphadenectomy is a curative approach.
- Complications include infection, anastomotic leakage, obstruction, adhesions, sexual dysfunction, and malabsorption syndromes.

NEOADJUVANT RADIATION THERAPY

- RT has a limited role in colon cancer because most recurrences are extrapelvic and occur in the abdomen. A subset of patients may benefit from neoadjuvant (preoperative) fluorouracil-based chemoradiation to improve resectability.

ADJUVANT CHEMOTHERAPY FOR COLON CANCER

- Administer adjuvant therapy after complete tumor resection to eliminate residual micrometastatic disease. Duration of therapy is usually 6 months. Adjuvant therapy is not indicated for stage I CRC because more than 90% of patients are cured by surgical resection alone.
- Offer adjuvant therapy with stage II disease at higher risk for relapse, with a detailed discussion regarding the potential benefits versus treatment-related toxicities.
- Adjuvant chemotherapy significantly decreases risk of cancer recurrence and death and is standard of care for stage III disease.
- Standard adjuvant regimens include a fluoropyrimidine (**fluorouracil** [with **leucovorin**] or **capecitabine)** as a single agent or in combination with **oxaliplatin.** Leucovorin enhances cytotoxic activity of fluorouracil.
- Continuous intravenous (IV) infusion of fluorouracil is generally well tolerated but is associated with palmar-plantar erythrodysesthesia (hand–foot syndrome) and stomatitis. Leukopenia is the dose-limiting toxicity of IV bolus administration. Both administration methods are associated with a similar incidence of mucositis, diarrhea, nausea and vomiting, and alopecia.
- In rare cases, patients deficient in dihydropyrimidine dehydrogenase, responsible for the catabolism of fluorouracil, develop severe toxicity, including death, after fluorouracil administration.
- National guidelines recommend the FOLFOX (fluorouracil/leucovorin and oxaliplatin) regimen as the preferred treatment for patients with stage III colon cancer who can tolerate combination therapy. Oxaliplatin is associated with both acute and persistent neuropathies, including rare, acute

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pharyngolaryngeal dysesthesia, neutropenia, and gastrointestinal (GI) toxicity.

- Oral capecitabine is an alternative to fluorouracil to improve safety and ease of administration.
- Selection of an adjuvant regimen (**Table 59-1**) is based on patient-specific factors, including performance status, comorbid conditions, and patient preference based on lifestyle factors. Consider age, as subset analysis has shown no overall survival (OS) benefit with oxaliplatin in those over 70 years.
- Fluorouracil/leucovorin regimens currently have limited use but are acceptable options in patients who cannot receive oxaliplatin and are unable to tolerate oral capecitabine.

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TABLE 59-1

Chemotherapy Regimens for the Adjuvant Treatment of CRC[a]

Regimen	Agents	Comments
FOLFOX[b]	Oxaliplatin 85 mg/m^2 IV on day 1 Leucovorin 400 mg/m^2 IV on day 1 Fluorouracil 400 mg/m^2 IV bolus, after leucovorin on day 1, then 1200 mg/m^2/day × 2 days CIV (total 2400 mg/m^2 over 46–48 hours) Repeat every 2 weeks × 24 weeks	Preferred regimen for stage III colon and rectal cancer; high-risk; common toxicities: sensory neuropathy, neutropenia
CAPEOX	Oxaliplatin 130 mg/m^2 IV day 1 Capecitabine 1000 mg/m^2 twice daily orally days 1–14 Each cycle lasts 3 weeks × 24 weeks	Improved DFS in patients with stage III colon cancer compared to capecitabine alone or Roswell Park regimen; common dose-limiting toxicities: neuropathies and hand–foot syndrome; a preferred regimen for adjuvant rectal therapy
Capecitabine	Capecitabine 1000 mg/m^2 to 1250 mg/m^2 PO twice daily on days 1–14 Each cycle lasts 14 days and is repeated every 3 weeks × 24 weeks	Hand–foot syndrome common, useful for patients without vascular access or who have difficulties with travel to infusion center
Roswell Park regimen	Leucovorin 500 mg/m^2 IV day 1 over 2 hour Fluorouracil 500 mg/m^2 IV bolus 1 hour after leucovorin Repeat weekly for 8 weeks × 4 cycles	Leukopenia, common dose-limiting toxicity, diarrhea, and stomatitis common
Simplified biweekly	Leucovorin 400 mg/m^2/day IV Fluorouracil 400 mg IV bolus, after leucovorin, then 1200 mg/m^2/day on days 1 and 2 (total 2400 mg/m^2 over 46–48 hours) for 2 consecutive days Repeat every 2 weeks × 12 cycles	Hand–foot syndrome common

CIV, continuous intravenous infusion; DFS, disease-free survival; IV, intravenously; PO, by mouth.

[a]National Comprehensive Cancer Network (NCCN) Guideline recommendations for adjuvant therapy. All recommendations are category 2A unless otherwise noted. Category 2A: based on lower evidence, there is uniform NCCN consensus that intervention is appropriate.

[b]Known as mFOLFOX6.

ADJUVANT THERAPY FOR RECTAL CANCER

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- Rectal cancer is more difficult to resect with wide margins, so local recurrences are more frequent than with colon cancer. Neoadjuvant chemoradiation followed by surgery and adjuvant chemotherapy or total neoadjuvant therapy (fluoropyrimidine-based chemotherapy followed by chemoradiation [or vice versa] followed by surgery) is recommended for stage II and III rectal cancer. FOLFOX and CAPEOX are the preferred chemotherapy regimens, but fluorouracil and leucovorin combination regimens and capecitabine can be used.

  ✓ Neoadjuvant chemoradiation significantly reduces local recurrence, has fewer toxicities, and improves the rates of sphincter-preserving surgeries as compared to postoperative chemoradiation. Offer preoperative RT alone to patients who cannot tolerate chemoradiation.

- Administer adjuvant chemotherapy to total 6 months of chemotherapy.

METASTATIC DISEASE

- Patients with metastatic colorectal cancer (MCRC) are considered to have resectable, potentially resectable, or unresectable metastatic disease. Surgery and RT are used to manage isolated sites of tumor. Chemotherapy is used for disseminated disease and is the primary treatment modality for unresectable MCRC.

- Tumor genotyping for *RAS* (*KRAS* and *NRAS*) and *BRAF* mutation status, *HER2* amplification, and determination of tumor methylation or mismatch repair (MMR) or MSI status (if not previously done) are recommended to identify appropriate treatment options.

RESECTABLE OR POTENTIALLY RESECTABLE MCRC

- Surgical resection of isolated metastases to the liver or lung increases probability of survival.

- Neoadjuvant or conventional chemotherapy is administered to increase complete resection rates with resectable and potentially resectable liver or lung lesions (**Table 59-2**). The choice of neoadjuvant therapy depends on patient-specific factors and includes FOLFOX, CAPEOX, FOLFIRI (infusional fluorouracil, leucovorin, and **irinotecan**), or FOLFOXIRI (infusional fluorouracil, leucovorin, oxaliplatin, and irinotecan). It is typically administered for 2–3 months before surgery. Adjuvant chemotherapy (preferably FOLFOX or CAPEOX) is administered to complete a total of 6 months of chemotherapy.

- The optimal sequencing of chemotherapy with initially resectable MCRC is controversial, as treatment options include surgery followed by chemotherapy or perioperative (pre- and postoperative) chemotherapy with surgery.

- Consider hepatic-directed therapy in addition to or as an alternative to surgical resection in patients with liver-only or liver-predominant MCRC. Hepatic artery infusion delivers chemotherapy (eg, **floxuridine** and fluorouracil) through the hepatic artery directly into the liver. Tumor ablation uses radiofrequency ablation or microwave energy to generate heat to destroy tumor cells. Cryoablation is also used. These strategies are less successful than surgical interventions.

TABLE 59-2

Initial Chemotherapeutic Regimens for MCRC[a]

Regimen	Agents	Comments
Patients Appropriate for Intensive Therapy with *RAS* Mutations		
FOLFOX +/− bevacizumab	Oxaliplatin 85 mg/m^2 IV day 1 Leucovorin 400 mg/m^2 IV day 1 Fluorouracil 400 mg/m^2 IV bolus, after leucovorin day 1, then 1200 mg/m^2/day × 2 days CIV (total 2400 mg/m^2 over 46–48 hours) Repeat every 2 weeks +/− Bevacizumab 5 mg/kg IV day 1 before FOLFOX	Most commonly used first-line regimen

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	Repeat cycle every 2 weeks	
CAPEOX +/− bevacizumab	Oxaliplatin 130 mg/m^2 IV day 1 Capecitabine 1000 mg/m^2 orally twice a day, days 1–14 Repeat cycle every 3 weeks +/− Bevacizumab 7.5 mg/kg IV day 1 Repeat cycle every 3 weeks	Reduced capecitabine dose is better tolerated; patient must be able to be adherent and report adverse drug reactions in a timely fashion
FOLFIRI +/− bevacizumab	Irinotecan 180 mg/m^2 IV day 1 Leucovorin 400 mg/m^2 IV day 1 Fluorouracil 400 mg/m^2 IV bolus, after leucovorin day 1, then 1200 mg/m^2/day × 2 days CIV (total 2400 mg/m^2 over 46–48 hours) +/− Bevacizumab 5 mg/kg IV day prior to FOLFIRI Repeat cycle every 2 weeks	May be preferred in patients who have preexisting neuropathy or those in which neuropathy may be debilitating to their line of work (eg, musician)
FOLFOXIRI +/− bevacizumab	Irinotecan 165–180 mg/m^2 IV day 1 prior to oxaliplatin Oxaliplatin 85 mg/m^2 IV prior to leucovorin day 1 Leucovorin 400 mg/m^2 IV day 1 prior to fluorouracil Fluorouracil 1200 mg/m^2/day × 2 days CIV (total 2400 mg/m^2 over 48 hour) Repeat cycle every 2 weeks +/− Bevacizumab 5 mg/kg IV day 1 before FOLFOXIRI Repeat cycle every 2 weeks	More neutropenia and peripheral neurotoxicity compared to FOLFIRI; often used in medically fit individuals with diffuse aggressive disease to palliate symptoms and as potential conversion therapy[b]
Patients Appropriate for Intensive Therapy with *RAS* or *BRAF* WT and Left-Sided Colon Tumors		
FOLFOX + cetuximab or panitumumab	FOLFOX regimen + cetuximab (400 mg/m^2 IV loading dose, then cetuximab 250 mg/m^2 IV weekly thereafter OR cetuximab 500 mg/m^2 IV every 2 weeks) before FOLFOX OR FOLFOX regimen + panitumumab 6 mg/kg IV day 1 before FOLFOX Repeat cycle every 2 weeks	Only *RAS* or *BRAF* WT and left-sided tumor
FOLFIRI + cetuximab or panitumumab	FOLFIRI + cetuximab (400 mg/m^2 IV loading dose, then cetuximab 250 mg/m^2 IV weekly thereafter OR cetuximab 500 mg/m^2 IV every 2 weeks) before FOLFIRI OR FOLFIRI + panitumumab 6 mg/kg IV day 1 before FOLFIRI Repeat cycle every 2 weeks	Only *RAS* or *BRAF* WT and left-sided tumor; preferred for patients with preexisting neuropathy or those in whom neuropathy may be debilitating to their line of work (eg, musician)

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CIV, continuous intravenous infusion; IV, intravenous.

[a]The NCCN Guideline recommendations for initial therapy. All recommendations are category 2A unless otherwise noted. Category 2A: based on lower evidence, there is uniform NCCN consensus that intervention is appropriate.

[b]The original dosing was 1600 mg/m^2/day; however, it is recommended that US patients use this dose as they do not tolerate fluorouracil as well

UNRESECTABLE MCRC

- Systemic chemotherapy palliates symptoms and improves survival with unresectable disease. RT may control localized symptoms. Most MCRCs are incurable; palliative chemotherapy prolongs and improves quality of life.
- Consider goals of therapy, history of prior chemotherapy, tumor *genotype* and status, performance status/comorbidities, and risk of drug-related toxicities to determine a management strategy. Regimens are the same for metastatic cancer of the colon and rectum.

  ✓ Most first-line chemotherapy regimens incorporate a fluoropyrimidine. Addition of **irinotecan** or oxaliplatin significantly improves response rates, progression-free survival (PFS), and median survival. Oxaliplatin in combination with fluorouracil-based regimens is associated with higher response rates and prolonged PFS, with variable effects on OS (see **Table 59-2**).
- Oral capecitabine can be used alone or in combination with oxaliplatin (CAPEOX).
- **Bevacizumab** is a recombinant, humanized monoclonal antibody that inhibits vascular endothelial growth factor (VEGF). Addition of bevacizumab to fluorouracil-based regimens modestly increases PFS and OS as compared to chemotherapy alone.

  ✓ Hypertension is common with bevacizumab and easily managed with oral antihypertensive agents. Other safety concerns include bleeding, thrombocytopenia, and proteinuria. GI perforation is a rare but potentially fatal complication necessitating prompt evaluation of abdominal pain associated with vomiting or constipation. Bevacizumab can interfere with wound healing; schedule surgery at least 6–8 weeks after the last dose of bevacizumab and wait at least 6–8 weeks after surgery to restart.
- **Cetuximab** and **panitumumab** are epidermal growth factor receptor (EGFR) inhibitors used in patients with wild-type *RAS* and *BRAF* tumors in combination with FOLFOX or FOLFIRI or administered alone (**Table 59-2**). Patients with left-sided primary tumors have improved OS when treated with EGFR inhibitors, while those with right-sided tumors (cecum to hepatic flexure) do not. Severe infusion reactions, including anaphylaxis, can occur with cetuximab (3%) and panitumumab (1%). Skin toxicity is commonly seen and is not part of the infusion reaction. The presence of papulopustular skin rash correlates with response and survival and most commonly occurs within 2–4 weeks of therapy initiation.
- **Trastuzumab** and **pertuzumab** are monoclonal antibodies directed against *HER2*. The combination of trastuzumab + pertuzumab or **lapatinib**, or **tucatinib** is recommended as an option with *HER2* amplification and wild-type *RAS* and *BRAF* tumors.
- Patients may receive multiple different regimens; the sequence of drugs appears less important than exposure to all active agents in the course of cancer treatments. Both FOLFIRI and FOLFOX are considered the reference standards in MCRC; their different toxicity profiles influence sequence of treatments.

METASTATIC DISEASE: SECOND-LINE AND SUBSEQUENT THERAPY

- The selection of second-line chemotherapy is primarily based on the type of and response to prior therapy received, site and extent of disease, and patient factors and treatment preferences. The optimal sequence of regimens has not been established (**Table 59-3**). **Trifluridine/tipiracil** is approved for treatment of MCRC patients who have been previously treated with a fluoropyrimidine-, oxaliplatin-, and irinotecan-containing regimens, an anti-VEGF targeted therapy, and an anti-EGFR monoclonal antibody if *RAS* wild-type.
- Patients with wild-type *RAS* and *BRAF* tumors who experience progression on therapies that do not contain an EGFR inhibitor may benefit from the combination of cetuximab or panitumumab and irinotecan, FOLFOX, or FOLFIRI.

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- A two-drug regimen of **encorafenib** (a *BRAF* inhibitor) and an EGFR inhibitor (cetuximab or panitumumab) is recommended to improve overall outcomes in second- and subsequent-line therapies for patients with *BRAF V600E* mutations.
- Angiogenesis inhibitors including VEGF inhibitors bevacizumab, **ramucirumab,** and **ziv-aflibercept** and the oral multikinase inhibitors **regorafenib** and **fruquintinib** may be used with progressive disease on other therapies.
- *HER2*, a member of the same kinase family as EGFR, is rarely overexpressed in CRC; however, it is more common with *RAS* and *BRAF* wild-type tumors. *HER2* inhibitor therapy can be an option with *HER2* overexpression when other options have failed.
- **Pembrolizumab,** a humanized, IgG4 monoclonal antibody that binds to PD-L1 with high affinity, is effective in MCRC with deficient MMR (dMMR), high tumor mutational burden, or *POLE*/*POLD1* mutations. **Nivolumab,** another humanized IgG4 monoclonal antibody PD-1 inhibitor, has also been evaluated with or without **ipilimumab** in patients with MCRC who have dMMR/high MSI (MSI-H) tumors.

TABLE 59-3

Second-Line and Salvage Chemotherapy Regimens for MCRC[a]

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Disease Progression with First-Line Regimen	Comments
Second-Line Options	
FOLFIRI or irinotecan + bevacizumab or ziv-aflibercept or ramucirumab	After previous oxaliplatin-based regimen (without irinotecan) (ie, FOLFOX, CAPEOX); use with caution in patients with elevated bilirubin; bevacizumab is the preferred antiangiogenic agent based on toxicity and cost
FOLFOX or CAPEOX ± bevacizumab	After previous irinotecan-based regimen (without oxaliplatin) (ie, FOLFIRI); bevacizumab FDA-approved to continue with second-line options
FOLFOX + cetuximab or panitumumab	After previous irinotecan-based regimen (without oxaliplatin) (ie, FOLFIRI); only if *RAS* WT and *BRAF* WT
FOLFIRI or irinotecan + cetuximab or panitumumab	After previous oxaliplatin-based regimen (without irinotecan) (ie, FOLFOX, CAPEOX); only if *RAS* WT and *BRAF* WT; if neither previously given; use with caution in patients with elevated bilirubin
Encorafenib + (cetuximab or panitumumab)	Only if *BRAF V600E* mutation positive
Nivolumab ± ipilimumab or dostarlimab or pembrolizumab	Only if dMMR/MSI-H or *POLE/POLD1* mutation
Trastuzumab + (pertuzumab or lapatinib or tucatinib)	Only if *HER2*-amplified and *RAS* and *BRAF* WT
Fam-trastuzumab deruxtecan-nxki	Only if *HER2*-amplified (IHC 3+)
Entrectinib or larotrectinib	*NTRK* gene fusion-positive
Selpercatinib	*RET* gene fusion-positive
Therapy after Second Progression or Third Progression (Can Use Any of the Previous Recommendations)	
Regorafenib	Used after progressing through all available regimens
Trifluridine/tipiracil ± bevacizumab	Used after progressing through all available regimens
Fruquintinib	Used after progressing through all available regimens
Clinical trial	If available and only if patient is eligible
Best supportive care	Appropriate for patients who do not want to pursue treatment, or not eligible for cancer-directed therapy, or if quality of life is expected to decrease

FDA, food and drug administration; *NTRK*, neurotrophic tyrosine receptor kinase; WT, wild-type.

[a]NCCN Guideline recommendations for second-line and subsequent therapy. All recommendations are category 2A unless otherwise noted. Category 2A: based on lower evidence, there is uniform NCCN consensus that intervention is appropriate.

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EVALUATION OF THERAPEUTIC OUTCOMES

- Goals of monitoring are to evaluate benefit of treatment and detect recurrence.
- Consult practice guidelines for specific follow-up after curative surgical resection, with or without adjuvant therapy.
- Monitor for anticipated side effects such as loose stools or diarrhea, nausea or vomiting, mouth sores, fatigue, and fever.
- Monitor closely for side effects that require prompt intervention, such as irinotecan-induced diarrhea, bevacizumab-induced GI perforation, hypertension and proteinuria, oxaliplatin-induced neuropathy, and cetuximab- and panitumumab-induced skin rash.
- Less than one-half of patients develop symptoms of recurrence, such as pain syndromes, changes in bowel habits, rectal or vaginal bleeding, pelvic masses, anorexia, and weight loss. Recurrences in asymptomatic patients can be detected by monitoring serum CEA levels.
- Monitor quality-of-life indices, especially in patients with metastatic disease.

See Chapter 158, Colorectal Cancer, authored by Kaylyn R. Collette and David L. DeRemer, for a more detailed discussion of this topic.

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